

REMARKS

Upon entry of this response and amendment, claims 4-10 are currently pending in the present application. Claim 4 has been amended to incorporate the limitations of claim 1 thereinto (with claim 1 being subsequently cancelled). Likewise, claims 8 and 9 have been amended to incorporate the limitations of claim 4 thereinto. The claims have been amended in the expectation that the amendments will place this application in condition for allowance. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

Claims 1, 3-8 and 10 stand rejected as being indefinite based on language contained within the claims. Claim 8 stands rejected as being anticipated by Malchesky (U.S. Patent No. 5,932,171). Claims 1, 3 and 9 stand rejected as being obvious over Rasmussen (U.S. Patent No. 3,996,126). Claims 4-7 and 10 would be allowable if rewritten to overcome the indefiniteness rejection and include all of the limitations of the base claim and any intervening claims from which the claims depend.

Based on the attached claim amendments and following remarks, Applicant respectfully submits that the present application is in condition for allowance.

1. Rejection of Claims 1, 3-8, and 10
under 35 U.S.C. § 112, 2d paragraph

Claims 1, 3-8 and 10 stand rejected under 35 U.S.C. § 112,

second paragraph as being indefinite. As a basis of this rejection, the Office Action states:

Claims 1, 3-8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. In claim 1, it is not clear as to what medium, solution or solution is/are applied in the method step; and in claim 8, it is not clear if there are two solutions which are separate streams. It is unclear what defines the terms medium and solution. Applicant's remarks on pages 4-5 describe two solution which are separate and independently used; however, the claims recite a single solution. In claim 7, it is unclear what is meant by "a pH of up to about 7-13". In claim 10, it is unclear if the steps are in addition to the step of claim 9.

Applicants respectfully traverse this rejection. Regarding the §112, second paragraph rejection, caselaw has defined two requirements under the statute: (1) whether the applicant has stated the invention as something elsewhere in the application which would not fall under the scope of the claims; and (2) whether the claims would be communicated with a reasonable degree of particularity and distinctness to a person skilled in the art in light of the content of the disclosure and the teachings of the prior art. MPEP §2171, §2173, and §2173.02.

Applicant has amended the claims to better clarify the present inventive subject matter. In particular, Applicant has amended claim 1 to clarify that both the aqueous predominantly anion-containing and aqueous predominantly cation-containing solutions are applied to a root canal. Thus, Applicant has removed the basis of the rejection of claim 1 as being

indefinite.

Likewise, Applicant has amended claim 8 to clarify that there are two solutions which are separate and independent product streams. In making this amendment, and the amendment to claim 1, Applicant specifically claims two separate and independent solutions used. The amendments clarify this subject matter. Applicant has, therefore, removed the basis of the rejection of the claims due to this inconsistency.

Applicant has further amended claims 7 and 10 to further clarify the subject matter claimed within the respective claims. In claim 7, Applicant has made clear that the pH of the cation-containing solution is between 7 and 13; while in claim 10, Applicant has clarified that the steps of claim 10 are supplemental to the steps in claim 9. In making such amendments, Applicant has removed the basis of the rejection of these claims as being indefinite.

Accordingly, Applicant respectfully submits that the claims are now definite and respectfully requests the Examiner to reconsider and withdraw the rejection of pending claims 1, 3-8 and 10.

2. Rejection of Claim 8 under 35 U.S.C. § 102(b)

Claim 8 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Malchesky (U.S. Patent No. 5,932,171).

As the basis of this rejection, the Official Action states:

Claim 8 is rejected under 35 U.S.C. 102(b) as being

anticipated by Malchesky (5,932,171). Malchesky discloses an irrigating medium comprising an electro-chemically activated, aqueous saline solution having microcidal, dispersing and surfactant properties (column 2, line 10). Malchesky also shows the solution producing a catholyte solution stream and anolyte solution stream. The recitation of intended use in the claim has not been given patentable weight.

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

As amended herein, claim 8 is directed to an irrigating medium for irrigating root canals. The irrigating medium comprises an electro-chemically activated, aqueous saline solution characterised in that it is electrochemically activated in an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a cathodic and an anodic chamber. The electro-chemically activated aqueous solution includes separable and both of an aqueous predominantly anion-containing solution and an aqueous predominantly cation-containing solution having microcidal as well as dispersing and surfactant properties.

Thus, in order for Malchesky to anticipate this claim, the reference must teach each and every limitation discussed above. Applicant respectfully submits that Malchesky fails to do so.

The two solutions (anolyte and catholyte) produced according to claim 8 are unique in that they not only each have their own unique characteristics and applications, but also often have strong synergistic roles to play in some specific applications. More specifically, Applicant's invention provides for two solutions which, although they are extremely effective in killing and controlling harmful microorganisms, remain harmless to humans and animals. Through appropriate control of feed materials and production conditions, the anolyte and catholyte included in the electro-chemically activated aqueous solution of claim 8, when compared to equivalent chlorinator products for example, tend to have a lower concentration of chlorine species and a higher concentration of a host of other oxidizing radicals. This ensures greater efficacy of the anolyte and catholyte through their synergistic effect. Further, where required, for example in sensitive root canal treatment applications, it is possible in terms of the present invention to produce products that are substantially free of chlorine.

The importance of the separate anolyte and catholyte solutions is especially apparent in applications where one does not wish to use chlorine because of damage to equipment or because of skin sensitivity. Those skilled in the art of root canals will appreciate that there are very specific challenges

when it comes to root canal treatment. Such treatment procedures generally involve a compromise between (i) proper cleaning and disinfecting of the root canal, but at a risk of coming into contact with jaw bone cells and causing necrosis of the same, or (ii) avoiding the risk of necrosis, but at a risk of improper cleaning the root canal and incomplete removal of infectious bacterial tissue. This is also the problem associated with prior art electrolyzed solutions that, although they may be suitable for use within a mouth cavity, may be wholly unsuitable and even dangerous for use in root canal treatment. The anolyte produced according to the present invention, and claimed in claim 8, not only permits total cleaning of the root canal, but at the same time has been demonstrated to be non-toxic and completely compatible with human tissue.

In order to obtain the anolyte and catholyte solutions as claimed in claim 8, the present inventive subject matter utilizes a cylindrical electrolytic device, having at least one electrolytic cell, in which the anodic and cathodic chambers are separated by a semi-permeable membrane and the specific design of which permits the harnessing of two distinct, separate and electrochemically different product streams of activated water, in a process known as electrolytic activation (EA) or electrochemical activation (ECA). More particularly, the electrolytic cell of the present invention (also known as a FEM-cell, which is short for "Flow-through Electrolytic Module") comprises a central rod, preferably used as the anode, around

which the concentric ceramic tube diaphragm is arranged. The outer tubular wall of the reactor is then used as the counter-electrode. In this example it would therefore be used as the cathode. The co-axial diaphragm separates an annular inter-electrode space between the two co-axial electrodes into a cathodic and an anodic chamber respectively. It is because of this particular electrochemical cell arrangement that the cation-rich and anion-rich streams are separable and can be applied particularly as two separate product streams, either simultaneously or consecutively. In addition, the electrochemical cell of the present invention provides for a much higher and more uniform electric field to which the solutions are exposed. This essentially provides for a higher level of ``activation'' of the solutions than that which is normally obtained with other types of electrolytic cells, particularly plate-type reactors.

Malchesky, on the other hand, discloses a water electrolysis apparatus that splits a water stream into two separate streams that respectively pass through an anode chamber and a cathode chamber. What Malchesky is describing in the patent is the known method of dividing a feed solution into two streams, sending one stream through the anodic chamber and the other through the cathodic chamber. In contrast, the present inventive subject matter involves sending the entire feed solution through one electrode chamber and thereafter recirculating all or part of the stream through the other

electrode chamber. It is due to this preparation and arrangement that the present inventive subject matter is able to control and modulate the characteristics of the anolyte and catholyte solutions that are claimed in claim 8.

By way of an illustrative example, the arrangement of the electro-chemical reactor in claim 8 allows the formation of the electro-chemically activated solution to be prepared as follows (which is not disclosed or taught by Malchesky). A dilute saline solution is fed into the cathodic chamber to produce an electrolyzed catholyte. Part of the catholyte is then introduced into the anodic chamber to produce an anolyte solution. Depending on the desired characteristics, the anolyte and/or catholyte solutions could then be reintroduced into the cathodic and/or anodic chambers for "tweaking". This can be repeated until the anolyte and catholyte possess the desired characteristics. Nowhere within the Malchesky patent is this arrangement and method disclosed.

Applicant respectfully reiterates that the electro-chemically activated aqueous solution as claimed in claim 8 and discussed above is not disclosed nor taught by Malchesky. By electro-chemically activating the saline solution in the manner as claimed by means of the through-flow electrochemical reactor and under the claimed conditions, the anolyte and catholyte solutions gain very specific properties. These properties are not attainable by the known method of electro-chemical activation in the plate-type reactors as taught by Malchesky.

Accordingly, Applicants respectfully submits that all of the limitations of the present inventive subject matter as claimed in claim 8 is neither disclosed, nor taught, by the Malchesky patent. As such, Applicant submits that the Examiner has failed to meet the burden of proving that claim 8 is anticipated by Malchesky. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of pending claim 8 as being anticipated by Malchesky.

3. Rejection of Claims 1, 3 and 9 under 35 U.S.C. § 103(a)

Claims 1, 3 and 9 stand rejected under 35 U.S.C. § 103(a) as being obvious over Rasmussen (U.S. Patent No. 3,996,126).

As the basis of this rejection, the Official Action states:

Claims 1, 3 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen (3,996,126). Rasmussen discloses a method for irrigating teeth including the step of applying an electro-chemically activated, aqueous saline solution to a tooth for irrigation purposes; however, Rasmussen does not show irrigating a root canal. It is held to be an obvious matter of choice to one of ordinary skill in the art that irrigating "all parts of the teeth" as disclosed by Rasmussen may include the root canal of a tooth. It is held to be an obvious matter of choice to one of ordinary skill in the art as to indefinite limitations of the solution, see paragraph 2.

Applicants respectfully traverse this rejection. The references of record do not teach or suggest applicant's inventive subject matter as a whole as recited in the claims. The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

Applicant notes, however, that the Examiner has indicated that claims 4-7 and 9 would be allowable if rewritten in independent form and amended to overcome the indefiniteness issues. Applicant has so amended claim 4 to incorporate the limitations of claim 1, from which claim 4 depends. Applicant has also amended claim 9 to incorporate the limitations of claim 4. Additionally, Applicant has amended the claims to overcome the indefiniteness issues, as is detailed above. Therefore, Applicant respectfully submits that the claims are allowable as written.

Accordingly, Applicant respectfully submits that the claims are not obvious over the cited reference, and respectfully requests reconsideration and with withdrawal of the rejection of the claims as being obvious over the Rasmussen patent.

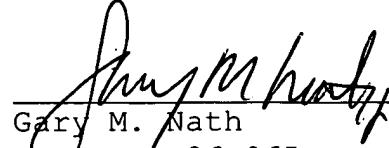
CONCLUSION

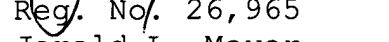
Following entry of this response and amendment, claims 3-10 are pending in this application. Applicant respectfully submits that, based on the amendments and remarks made herein, claims 3-10 are patentable over the prior art of record. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the outstanding rejections of claims 3-10 and allow all pending claims resented herein.

Respectfully submitted,

NATH & ASSOCIATES PLLC

Date: April 18, 2003


Gary M. Nath
Reg. No. 26,965


Jerald L. Meyer
Reg. No. 41,194
Customer No. 20529

NATH & ASSOCIATES PLLC

1030 Fifteenth Street, N.W.
Sixth Floor
Washington, D.C. 20005-1503
Telephone: (202) 775-8383
Facsimile: (202) 775-8396
GMN:JBG:\roa2.wpd

CLAIMS

D17 1. [Cancelled]

2. [Cancelled]

3. (Currently amended) The method of claim ± 4, wherein the aqueous predominantly anion-containing solution and the aqueous predominantly cation-containing solution are prepared by means of electrolysis of an aqueous solution of a salt.

C1 4. (Currently amended) The method of claim 1 wherein the anion-containing and the cation-containing solution are produced by A method for treating root canals, the method comprising the steps of: electrochemically activating an aqueous solution in an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into cathodic and anodic chambers, wherein the electro-chemically activated solution includes an aqueous predominantly anion-containing solution and an aqueous predominantly cation-containing solution having microcidal, as well as dispersing and surfactant, properties; and applying the aqueous and predominantly anion-containing solution and aqueous predominantly cation-containing solution either concurrently or successively to a root canal.

5. (Currently amended) The method of claim ± 4 wherein the anion-containing solution is produced from a 10% aqueous

NaCl solution, electrolysed to produce separable activated or excited radical cation and radical anion species, the anion-containing solution having ~~an extremely high~~ a redox potential of up to about +1170 mV.

6. (Currently amended) The method of claim 1 4 wherein the anion-containing solution has a pH of about 2 to 7 and a redox potential of about +1170 mV.
7. (Currently amended) The method of claim 1 4 wherein the cation-containing solution has a pH of ~~up to about between~~ 7 and 13 and a redox potential of about -980 mV.
8. (Currently amended) An irrigating medium for irrigating root canals, the irrigating medium comprising an electro-chemically activated, aqueous saline solution wherein characterized in that it is electrochemically activated in an electro-chemical reactor comprising a through-flow, electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a cathodic and an anodic chamber, wherein the electro-chemically activated aqueous solution includes both an aqueous predominantly anion-containing solution and an a separate aqueous predominantly cation-containing solution having microcidal as well as dispersing and surfactant properties.
9. (Currently amended) A method of irrigating root canals including, the method comprising the steps of electrochemically activating an aqueous solution in an electro-chemical reactor comprising a through-flow,

electro-chemical cell having two co-axial electrodes with a co-axial diaphragm between them so as to separate an annular inter-electrode space into a cathodic and an anodic chamber, such that the electro-chemically activated aqueous solution includes separable and both of an aqueous predominantly anion-containing and an aqueous predominantly cation-containing solution having microcidal, as well as dispersing and surfactant properties; and applying an electro-chemically activated, aqueous saline solution the aqueous predominantly anion-containing and aqueous predominantly cation-containing solution either concurrently or successively to a root canal for irrigation purposes.

10. (Currently amended) The method as claimed in claim 9 further including the steps of first applying cation-containing solution to the root canal, aimed at removing organic film and debris covering the inner walls of the root canal, and thereafter applying an anion-containing solution to the root canal, aimed at disinfecting the inner walls of the root canal and dentinal tubules.